REMARKS

Claims 1-5, 10-13, 15, 17-21 and 23-47 are pending in the application. Claims 6-9, 14, 16 and 22 have been previously cancelled. Claims 2-4, 12-13, 15, 20-21, 24-25, 27-30, 33-38, and 44-45 are listed by the Examiner as withdrawn. Thus, Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, 46 and 47 are presented for examination.

Rejection under 35 U.S.C. 112, First Paragraph

Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses this rejection. Moreover, this rejection is moot in view of the above amendment to claim 47.

Rejection under 35 U.S.C. § 103(a)

Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43 and 46-47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Harish et al., WO 02/26162 (Harish) combined with Alt, US 7,713,297 (Alt). Applicant respectfully traverses this rejection.

As noted by the Office, Harish teaches an implantable device coated on preselected regions/portions of its outer surface with therapeutic agent. The therapeutic agent is deposited on the surface of the device in the form of a dry stream of particles. The device is covered by a polymeric primer prior to applying the therapeutic particles to adhere the particles to the surface of the stent. The particles may be made of any substance suitable for loading onto implantable devices in solid form, including, but not limited to therapeutic substances or agents, radioisotopes, radiopaque substances, polymers, proteins, and nucleic acids (page 8, 1st full paragraph). Lists of therapeutic substances, radioactive/radiopaque substances, polymeric materials (including bioabsorbable polymers, polymeric biomolecules, and biostable polymers), proteins and nucleic acids are found on pages 9-11. The particles can be spherical having diameter from about 5 to 20 microns. The layer containing the particles can be covered by a polymeric topcoat that helps immobilize the particles on the surface of the device and controls the release of the therapeutic agents from the surface of the device. Individual particles within the stream may or may not be of uniform composition, as individual particles within a stream may be made of the same substance(s) or of different substances (page 12, last paragraph).

The Office Action further argues that "[a]lthough Harish teaches therapeutic particles coated as dry powder on a stent by virtue of adhesive [primer layer], and further teaches the particles may be made of different substances including biostable and radio-opaque substances, and although the reference teaches combination of the therapeutic agents, which implies that inevitable some particles surround other forming pockets, however, the reference does not explicitly teach the therapeutic agent and the microparticles are separate entities as instantly claimed by amended claim 1, or specific materials being metallic or ceramic as claimed in claim 47."

In an attempt to make up for these deficiencies, the Examiner turns to Alt. As noted in the Office Action, Alt teaches a stent coated with layer of metal particles having radio-opacity greater than the stent material to provide high visibility of viewing the stent by fluoroscopy during stent deployment in the body. The particles form interstices therebetween that act as repositories for retaining and dispensing therapeutic agents for time release therefrom after implantation of the stent.

More particularly, in Alt, particulate or powder metal is applied to a base layer surface and tightly bonded thereto, and built up to the desired layer thickness of high porosity by forming an interconnected multiplicity of the particles (microspheres), through application of heat. Alt, col. 8, lines 12-23. The metal particles are noble metals, specifically a platinum alloy with a small amount of iridium. See Alt Abstract and col. 7, line 61 to col. 8, line 11.

Thereafter, Alt infuses the therapeutic agent into the previously formed porous layer by infusion of a therapeutic-agent-containing solution. See Alt at col. 3, line 23 to col. 4, line 13.

On the basis of the above teachings, the Office urges that the presently claimed invention is obvious, specifically arguing as follows (emphasis added):

> Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention ***to provide an implantable device coated with dry powdered particles of combination of therapeutic agents, including biomolecules and radiopaque substances adhered to the surface of the device by primer as taught by Harish, and further add radio-opaque metallic particles to the therapeutic particles of Harish wherein the metallic particles form interstices containing the therapeutic particles therebetween as taught by Alt.*** One would have been motivated to do so because Alt teaches that metal particles provide high visibility of viewing of the stent by fluoroscopy during stent deployment in the body, and because Alt teaches that the particles form interstices therebetween that act as repositories for retaining and dispensing therapeutic agents for time release therefrom after implantation of the stent. ***One would reasonably expect***

formulating an implantable device coated with dry powdered particles of therapeutic agents and metallic radio-opaque particles containing the therapeutic agent therebetween and adhered to the surface of the device wherein the device has high visibility during deployment and timely releases active agents after implantation.

Applicant respectfully disagrees.

In would not be obvious to provide an implantable device coated with dry powdered particles of combination of therapeutic agents, including biomolecules and radiopaque substances adhered to the surface of the device by primer as taught by Harish, and further add radio-opaque metallic particles to the therapeutic particles of Harish wherein the metallic particles form interstices containing the therapeutic particles therebetween as taught by Alt.

Moreover, one would not have arrived at the presently claimed invention by doing so. In this regard, claim 1 requires a "medical article comprising: (a) an adhesive region comprising an adhesive; (b) a therapeutic agent, wherein at least a portion of said therapeutic agent is adhered to a surface of said adhesive region; and (c) microparticles, at least a portion of which are adhered to said surface of said adhesive region…"

This is true, for example, because the adhesive region (i.e., prepolymer) and therapeutic agents taught by Harish would be removed by the process of forming the porous coating that is taught by Alt.

Specifically, in the process taught by Alt, particulate or powder metal is applied to a base layer surface and tightly bonded thereto, and built up to the desired layer thickness of high porosity by forming an *interconnected* multiplicity of the particles (microspheres), through *application of heat*. Alt, col. 8, lines 12-23. The metal particles are noble metals, specifically a platinum alloy with a small amount of iridium. See Alt Abstract and col. 7, line 61 to col. 8, line 11. The process is a high temperature one, as the melting points of platinum and iridium are at the (white-hot) temperatures of 1773°C and 2450°C, respectively (Merck Index, Twelfth Edition), and it would clearly burn off any polymeric primer and therapeutic agent applied to the surface.

Moreover, even if the therapeutic agent were subsequently applied to the thus-formed porous layer (i.e., in the form of an infusion as taught by Alt), one would not arrive at the presently claimed invention, wherein therapeutic agent is applied to a surface of an adhesive region such that at least a portion of the therapeutic agent is adhered to a surface of the adhesive region.

For at least the above reasons, reconsideration and withdrawal of the rejection of the claims under 35 USC 103(a) are respectfully requested.

Conclusion

Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicants' attorney at 703-433-0510 in order that any outstanding issues be resolved.

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Respectfully submitted,

/David B. Bonham/
David B. Bonham
Registration No. 34,297

Attorney for Applicant
Mayer & Williams PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
Tel.: 703-433-0510
Fax: 908-518-7795